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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,515	05/25/2000	Jay M. Short	DIVER1370-4	9360

20985 7590 10/11/2002

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/11/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,515

Applicant(s)

SHORT ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 18 and 41-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 41-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Claims 18, 41-71 are pending.

Applicant's amendment of claim 18, cancellation of claims 1-17, 19-40, and addition of claims 41-71, in Paper No. 11, filed on 8/2/2002, is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 9/13/2002 was filed after the mailing date of the first Office Action on 3/27/2002. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

2. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 09/318528 filed on 5/25/1999, 09/291931, filed on 4/13/1999, 09/259214, filed on 3/1/1999 and 08/910798 filed on 8/13/1997.

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Claim Objections

3. Claims 41, 57 are objected to due to the recitation of "containing the nucleic acid sequence encoding said phytase". For clarity, it is suggested that the term "sequence" be deleted. Appropriate correction is required.

4. Claims 42, 58 are objected to due to the recitation of "said nucleotide sequence is preceded by a polynucleotide sequence encoding a signal peptide operably linked to said...sequence". For clarity, it is suggested that the claim be amended to recite "said phytase-encoding nucleic acid is operably linked to a polynucleotide encoding a signal peptide" or similar. Appropriate correction is required.

5. Claims 43, 59 objected to due to the recitation of "nucleic acid sequence is operably linked to ..". For clarity, it is suggested that the term "sequence" be deleted. Appropriate correction is required.

6. Claims 47-49, 63-65 are objected to due to the recitation of "foodstuff" and "animal feed" interchangeably. For clarity, it is suggested that only one term be used: "animal feed" or "foodstuff". Appropriate correction is required.

7. Claim 55 is objected to because of the following informalities: the term "ceils" has been misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 18, 41-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. Claims 18, 56 (claims 41-55, 57-71 dependent thereon) are indefinite in the recitation of "providing a plant cell, plant part or plant that contains a recombinant expression system" for the following reasons. As known in the art, a recombinant expression system comprises a vector and a host cell, therefore it is not clear how a plant cell can contain a vector and a host cell. It is suggested that if the intended meaning of the term "recombinant expression system" is "vector", the claims be amended accordingly. For examination purposes, the term "recombinant expression system" will be interpreted as "vector". Correction is required.
11. Claims 18, 56 (claims 41-55, 57-71 dependent thereon) are indefinite in the recitation of "system comprising a phytase-encoding nucleic acid sequence having a nucleotide sequence" as it is unclear and confusing. It is suggested that if the "system" (vector, see above) comprises a phytase-encoding nucleic acid, the claim be amended by deleting the term "sequence" after the term "acid". Correction is required.
12. Claims 18, 56 (claims 41-55, 57-71 dependent thereon) are indefinite in the recitation of "nucleotide sequence is expressed as a polypeptide" as it is unclear how a sequence can be expressed. As known in the art, it is nucleic acids which are expressed into proteins whereas sequences are just graphical representations of the order at which nucleotides/amino acids are arranged. It is suggested that the term "nucleotide sequence" be replaced with "nucleic acid" or similar. Correction is required.

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13. Claims 51 and 67 are indefinite in the recitation of "plant comprises seeds containing phytase to be used...." as it is unclear if the phytase being referred to is the phytase encoded by the polynucleotide of SEQ ID NO: 1 or if a different phytase can be in the seeds. It is suggested that if the plant comprises seeds containing the phytase encoded by the polynucleotide of SEQ ID NO: 1, the claim be amended accordingly. For examination purposes, the claim will be interpreted as "the method of claim 18 wherein the plant comprises seeds containing other phytases beside the one encoded by the polynucleotide of SEQ ID NO: 1". Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 51 and 67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 51 and 67 are directed to a method to produce an animal feed using a phytase encoded by the polynucleotide of SEQ ID NO: 1 wherein a plant contains a recombinant vector which comprises the polynucleotide of SEQ ID NO: 1 and wherein the plant comprises seeds containing a genus of phytases. See claim interpretation above. While the specification discloses a method to produce an animal feed wherein the phytase encoded by the polynucleotide

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of SEQ ID NO: 1 is used, there is no disclosure of other phytases or methods to produce an animal feed as described above wherein the plant contains a vector which expresses the phytase encoded by the polynucleotide of SEQ ID NO: 1 and further comprises seeds containing other phytases. The specification only discloses one phytase which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genus of phytases required for the claimed method. Thus, one skilled in the art cannot reasonably conclude that Applicant had possession of the claimed invention at the time the instant application was filed.

16. This rejection may be overcome by amending the claim to clearly indicate that the phytase in the seeds is that encoded by the polynucleotide of SEQ ID NO: 1.

17. Claims 51 and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to produce an animal feed wherein a plant contains a recombinant vector comprising the polynucleotide of SEQ ID NO: 1 and wherein the plant comprises seeds containing the phytase encoded by the polynucleotide of SEQ ID NO: 1, does not reasonably provide enablement for said method wherein the seeds can contain any phytase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the claims is not commensurate with the enablement provided due to the large number of unknown phytases encompassed by the claims. As indicated above, the specification does not provide any information as to other phytases except for that of SEQ ID

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NO: 2 (encoded by the polynucleotide of SEQ ID NO: 1). In addition, no disclosure of the critical structural elements required to display phytase function has been provided. While one could argue that other phytases can be isolated by sequence comparison using the polynucleotide of SEQ ID NO: 1 or the polypeptide of SEQ ID NO: 2, the state of the art clearly teaches the unpredictability of the art in regard to assigning function based on homology. Bork (Genome Research, 10:348-400, 2000) teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* were found to be hydroxylases once tested for activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring *Pseudomonas* enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. (Science 282:1315-1317, 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase.

Since the amino acid sequence determines the function of a polypeptide, one would require some knowledge and/or guidance as to how structure relates to function to isolate polypeptides of phytase activity and practice the claimed method. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to maintain the desired function, and the unpredictability of the prior art in regard to function based on homology, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to screen and isolate those polypeptides, as encompassed by the claim, with phytase activity, to practice the claimed method. Thus,

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Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

18. This rejection may be overcome by amending the claim to clearly indicate that the phytase in the seeds is that encoded by the polynucleotide of SEQ ID NO: 1.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 18, 41-71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6183740. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not

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patentably distinct from each other. Claims 1-5 of U.S. Patent No. 6183740 are directed to a method for improving the nutritional value of foodstuff by contacting a phytase identical to that of the instant application (SEQ ID NO: 2; encoded by the polynucleotide of SEQ ID NO: 1) with foodstuff so that inorganic phosphate is liberated from phytate contained in the foodstuff. Claims 18, 41-71 of the instant application are directed to a method to produce an animal feed comprising recombinantly producing the phytase of SEQ ID NO: 2 (encoded by the polynucleotide of SEQ ID NO: 1) in a plant, plant cell or plant part, and using the plant, plant cell or plant part in a composition suitable for an animal feed. The method of claims 1-5 of U.S. Patent No. 6183740 is not different from that of claims 18, 41-71 of the instant application because in both methods the same recombinant phytase is added to the animal feed or foodstuff for the liberation of inorganic phosphate from the phytate in the animal feed. The use of plant, plant parts or plant cells to make the phytase recombinantly, as recited in claims 18, 41-71 of the instant application, would have been obvious to one of skill in the art. One of skill in the art would have been motivated to do so for the benefit of providing additional nutritional elements found in the plant. One of ordinary skill in the art has a reasonable expectation of success at making the phytase recombinantly in plant cells, plant or plant parts since transformation of cells or plants is well known and widely used in the art. Therefore, the instant invention as a whole would have been prima facie obvious to a person of ordinary skill in the art.

21. Claims 18, 41-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of copending Application No. 09/777566. An obviousness-type double patenting rejection is appropriate

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where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 13 of copending application No. 09/777566 is directed to a method of recombinantly making a phytase identical to that of the instant application in plant cells, plant parts or plants and converting said plant cells, plant parts or plants into a composition suitable for animal feed. Claims 18, 41-71 of the instant application are directed to a method to produce an animal feed comprising recombinantly producing the phytase of SEQ ID NO: 2 (encoded by the polynucleotide of SEQ ID NO: 1) in a plant, plant cell or plant part, and using the plant, plant cell or plant part in a composition suitable for an animal feed. The method of claim 13 of copending application No. 09/777566 is not different from that of claims 18, 41-71 of the instant application because both methods require (1) the recombinant production of the same phytase in plant cells, plant parts or plants and (2) processing of such plant cells, plant parts or plants into a composition suitable for animal feed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 18, 41-71 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 18 of copending

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Application No. 09/866379. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-5 and 18 are directed to a method for improving the nutritional value of a phytate-containing foodstuff comprising adding a phytase identical to that of the instant application to the foodstuff or to a method to produce animal feed comprising recombinantly producing the same phytase as that of the instant application in a plant, plant cell or plant part, and using the plant, plant cell or plant part in a composition suitable for an animal feed. The methods of claim 1-5 and 18 of copending application No. 09/866379 are not different from that of claims 18, 41-71 of the instant application because in all these methods the same phytase is added to foodstuff to aid in the liberation of inorganic phosphate from the phytate in foodstuff. The use of plant, plant parts or plant cells to make the phytase recombinantly, as recited in claims 18, 41-71 of the instant application and the addition of the phytase or phytase-containing plant material to foodstuff, would have been obvious to one of skill in the art. One of skill in the art would have been motivated to do so for the benefit of providing additional nutritional elements from plants. One of ordinary skill in the art has a reasonable expectation of success at making the phytase recombinantly in plant cells, plant or plant parts since transformation of cells or plants is well

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known and widely used in the art. Therefore, the instant invention as a whole would have been prima facie obvious to a person of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. It is noted that parent application Serial No. 08/910,798 is not available to the Examiner at this time, therefore no determination has been made as to if or how the claims in said parent application were restricted. If, upon availability of the above parent application to the Examiner, it is determined that there is no ground(s) for a double patenting rejection due to a previous restriction requirement, the corresponding rejections will be withdrawn.

24. It is noted that applications Serial No. 10/156660 and 10/034985 disclose a polynucleotide of 100% sequence homology to SEQ ID NO: 1 and a polypeptide of 100% sequence identical to SEQ ID NO: 2 of the instant application. Since applications Serial No. 10/156660 and 10/034985 are not available to the examiner at this time, no determination has been made as to whether or not a double patenting rejection should be applied to the claims of the instant application. If, upon availability of the above application to the examiner, it is determined that there are conflicting claims between application Serial No. 10/156660 or 10/034985 and the instant application, double patenting will not be considered as new ground(s) of rejection.

Conclusion

25. No claim is in condition for allowance.

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26. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

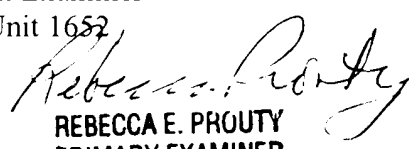
27. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DR
October 10, 2002

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652


REBECCA E. PROUTY
PRIMARY EXAMINER
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1600